

## REMARKS/ARGUMENTS

Claims 1-12 remain in the application.

### Objections to Claims

The Examiner has objected to claims 7-11 for improper multiple dependency. Claims 7-11 have been amended into proper dependent format for further consideration.

### Claim Rejections under 35 USC § 102(b):

The Examiner has maintained the 35 USC § 102(b) rejections of claims 1-4 and 12 in view of the following references. (1) Nickel *et al.*, US 6,093,704; (2) Nickel *et al.*, US 6,696,428; and (3) Nössner *et al.*, US 6,172,050. Furthermore, the Examiner stated that “applicant’s claims are directed to a method of using the claimed alkylphosphocholine compounds ‘for the manufacture of a drug product for the treatment of benign oncoses before and/or during treatment’ with the claimed anti-tumor substances. Claim 12 is drawn to a drug product comprising an alkylphosphocholine of formula I or II ‘for use in the treatment of benign and malignant oncoses with an approved antitumor substance.’” In view of a telephonic interview with the Examiner on August 17, 2005, the claims have been amended to clarify that the scope of the claims is drawn to a method of treating. Therefore, it is decidedly apparent that the intended use of the claimed invention is patentably distinguishable from the prior art.

Manual of Patent Examining Procedure (MPEP) 2131 provides, under 35 USC §102,

“A claim can be rejected only if each element of the claim is disclosed in a single prior art reference. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as is contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).”

Nickel *et al.*, (US 6,093,704), Nickel *et al.*, (US 6,696,428), and Nössner *et al.*, (US 6,172,050), fail to teach or suggest, either expressly or inherently, each and every element of the claimed invention. The scope of the presently claimed invention is the administration of the expressly claimed alkylphosphocholines in combination with antitumor substances, more specifically suitable cytostatics, for treating benign and malignant tumor diseases. See claims 1 through 12 (as amended).

By comparison, Nickel *et al.*, (US 6,093,704), Nickel *et al.*, (US 6,696,428), teach a method of treating side effects. More specifically, Nickel *et al.*, (US 6,093,704) describes a composition and method of using alkylphosphocholines, such as miltefosine, in conjunction with an **appetite-stimulating dopamine receptor antagonist to treat the side effect of a decrease in body weight** caused by administration of alkylphosphocholines in tumor therapy. Appetite-stimulating dopamine receptor antagonists are not specified as antitumor substances in the present invention. Thus Nickel *et al.*, (US 6,093,704), fails to teach the use of alkylphosphocholines in combination with antitumor medicaments, more specifically suitable cytostatics, for treating benign and malignant tumor diseases. Similarly, Nickel *et al.*, (US 6,696,428) describes a composition and method of using alkylphosphocholines, such as octadecyl (1,1-dimethylpiperidinio-4-yl)phosphate, in conjunction with an appetite-stimulating dopamine receptor antagonist to **treat the side effect of a decrease in body weight caused by** administration of the alkylphosphocholine in tumor therapy, **wherein the amount of appetite-stimulating dopamine receptor antagonist used is not effective for the treatment of said cancer sensitive to the said alkylphosphocholine**. Thus, both Nickel references fail to teach or suggest the explicit limitation of combining the alkylphosphocholines with antitumor substances and thereby do not anticipate the claimed invention.

Similarly, Nössner *et al.*, (US 6,172,050) does not teach or suggest combining the alkylphosphocholines of the references with antitumor medicaments. Nössner *et al.* (US 6,172,050) describes in column 19, lines 48-54 the activity of alkylphosphocholines **alone without** a combined composition or administration with other cytostatics. Thus, the claimed combination is novel and none of the cited references describe such a combination.

Thus, Applicants respectfully submit that the rejection of claims 1-4 and 12 under 35 USC § 102(b) is overcome and withdrawal thereof is requested.

**Claim Rejections under 35 USC § 103(a):**

The Examiner rejected claims 1, 2, and 12 under 35 USC § 103(a) as being unpatentable over Engel *et al.* (US 5,942,639) in view of Nickel *et al.*, (US 6,093,704). According to the Examiner, Engel *et al.* fails to teach the specified use of these compounds in pharmaceutical compositions. However, Engel *et al.* combined with the teachings of Nickel *et al.*, (US 6,093,704) would make it obvious to modify the alkylphosphocholines disclosed in the Engel *et al.* reference into the present claimed invention. Additionally, the Examiner brought attention to the ambiguity of the scope of the claims- “intended use of the claimed drug products as well as the claimed method of using for using alkylphosphocholine compounds (formula (I) and (II)) for making a drug product to be used in a combination treatment method.” Furthermore, the Examiner highlighted claim 12 as drawn to a drug product comprising an alkylphosphocholine of formula I or II ‘for use in the treatment of benign and malignant oncoses with an approved antitumor substance.’”

The claims have been amended to clarify that the scope of the claims 1-11 are drawn to a method of treating, and claim 12 has been clarified to emphasize administration of the alkylphosphocholine containing drug product before and/or during the treatment with an approved antitumor substance. Therefore, based on the amendments to the claims, the claimed invention is patentably distinguishable from the prior art and thus, claims 1, 2, and 12 are not rendered unpatentable over Engel *et al.* (US 5,942,639) in view of Nickel *et al.*, (US 6,093,704). Accordingly, the rejection of claims 1, 2 and 12 under 35 U.S.C. § 103(a) are overcome and withdrawal thereof is respectfully requested.

**Double Patenting:**

The Examiner has maintained the rejection claims 1, 3, 4, and 12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of US 6,172,050. The applicant reasserts the same objection as presented in the previous response dated May 3, 2005. The Applicants respectfully traverse the Examiner’s nonstatutory double patenting rejection. Applicants

submit that the cited patent references are assigned to the company ASTA Medica, which was the former, or predecessor, company of Zentaris (the current assignee of the present invention). Furthermore, the inventor Jürgen Engel is a common inventor in the present application and in all of the cited references used in the 35 USC § 102(b) rejections. However, the Applicants find that the Examiner has failed to make a *prima facie* case of obviousness regarding the use of alkylphosphocholines in combination with antitumor medicaments, more specifically suitable cytostatics, for treating benign and malignant tumor diseases and therefore withdrawal of the double patenting rejection is respectfully requested.

**Conclusion:**

Based on the foregoing amendments and remarks, favorable consideration and allowance of all of the claims now present in the application are respectfully requested.

Should the Examiner require or consider it advisable that the specification, claims and/or drawings be further amended or corrected in formal respects in order to place the case in condition for final allowance, then it is respectfully requested that such amendment or correction be carried out by Examiner's Amendment and the case passed to issue. Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, the Examiner is invited to telephone the undersigned.

The Commissioner is authorized to charge any required fees, including any extension and/or excess claim fees, any additional fees, or credit any overpayment, to Goodwin Procter LLP Deposit Account No. 06-0923.

Respectfully submitted for Applicant,



Ann-Marie Koss (Reg. No. 54,237)

GOODWIN PROCTER LLP

599 Lexington Avenue

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New York, NY 10022

(212) 459-7434